

Claims 2, 12, 13 and 18 have been rewritten in response to the Examiner's statement that such claims as previously pending in the application "would be allowable if rewritten in independent form" (page 4, October 1, 1999 Office Action).

Rejection under 35 U.S.C. § 102(b)

The Examiner has rejected claims 1, 3, 7, 8, 9, and 15 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,868,844 issued to Nunan (hereinafter "Nunan"). Claim 1 has been amended herein to patentably distinguish the physical structure of the present invention over Nunan. Claims 3, 7, 8, 9, and 15 depend from claim 1 and include all limitations of the parent claim. Hence claims 3, 7, 8, 9, and 15 are rendered patentably distinct over Nunan by the above amendment to claim 1.

Nunan discloses:

A multileaf collimator is formed of a multiplicity of heavy metal bar leaves driven relative to frames which are driven relative to jaws of a rectangular field collimator by electric motors and flexible cables. (Nunan, Abstract, emphasis added).

These irregular field shapes [of the collimator] can be varied during rotation of the radiotherapy machine gantry by driving the individual leaves with respect to their frame and driving the frame with or [sic] respect to the corresponding jaw. (Nunan, Col.3, ll.33-5, emphasis added).

Nunan discloses a multileaf collimator in which each leaf (or diaphragm) is moved with respect to the frame holding it to shape the collimator opening, with each leaf having its own associated drive and drive transmission means. Additionally, each of the two frames that hold the leaves of the collimator is translationally moveable relative to the jaws of the head of a radiotherapy machine. (Nunan, Col. 3, ll. 22-4, *see also* Nunan, Figure 8, items 24, 25, 26, and 27, described at Col. 6, ll. 54-66).

Claim 1 has been amended herein to explicitly include the limitation that the guiding block of the present invention is static. This structural element is rigidly fixed in relative position to the remainder of the apparatus (with the obvious exceptions of the diaphragms and their associated driving transmissions). The guiding block is not actuatable, and does not actively contribute to the shape or size of the collimator opening formed by the

diaphragm elements. Its sole purpose is to provide a static and rigid array of guide grooves, within which the diaphragms' movement is restricted to a translational direction. This claim limitation is in contrast to (and renders the present invention structurally patentably distinct over) the frame of Nunan. The Nunan frame not only holds the translationally slideable leaves, but is itself an important element in the size and shape of the achievable collimator opening by virtue of being itself translationally moveable with respect to the jaws of the radiotherapy machine to which it is attached.

As amended herein, all rejected claims of the present invention include the limitation of a static guiding block; Nunan lacks this limitation. "Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference." *Scripps Clininc & Research Foundation v. Genetech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991). "There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." *Id.*

Antecedent basis for the inclusion of the limitation of a static guiding block in claim 1 is found in the written description, by reference primarily to Figures 2A, 4, and 5, and additionally to Figures 1 and 3, and also in the structural description spanning pages 6 and 7.

Rejection under 35 U.S.C. § 103(a)

Applicants acknowledge their duty of candor under 37 C.F.R. § 1.56, and hereby assert that the subject matter of all claims was commonly owned at the time the invention covered therein was made.

The Examiner has rejected claims 4, 5, 6, 10, 11, 14, 16, 17, and 20 under 35 U.S.C. § 103(a) as being unpatentable over Nunan. The Examiner stated that Nunan discloses all of the elements of Applicant's claimed invention except for the guide block having grooves for the collimator plates, the detachable coupling of the power transmitting elements, and the position sensing means. The Examiner took Official Notice that grooved housings for collimator plates and position sensing means are well known in the collimator art, and additionally stated that the detachability of power transmitting

elements would have been obvious to one of ordinary skill in the art, motivated by ease of replacement. Applicants respectfully disagree and traverse all rejections.

Radiation therapy involves the exposure of tumors within a patient's body to an intense source of ionizing radiation, in an attempt to kill the cancer cells residing therein. To minimize the deleterious effects of the radiation on normal, healthy tissue; exposure of such healthy tissue to the radiation must be minimized. The more precisely the incident exposure pattern of radiation can be managed to the size and shape of the tumor, the more effective the radiation therapy is in killing the cancer cells, and the less damage is done to surrounding healthy tissue. The development in the art of collimators to effect this precise radiation beam shaping is in response to the ever-increasing precision with which the tumor's size and shape can be precisely determined through advances in medical imaging technology. Nunan was an early response to the need for precise beam shaping under computer control.

A significant disadvantage of early-generation actuated-plate beam collimators was the precision with which arbitrarily shaped – particularly curved – tumor outlines could be approximated with a series of adjacent square-ended plates. The closest approximation possible is a step-function, which necessarily either exposes all the tumor and significant additional surrounding healthy tissue, or protects surrounding tissue and partially hides the tumor from irradiation. This problem of accurately matching curved tumor shapes with square-ended collimator plates is more fully discussed in U.S. Patent No. 5,889,834 issued to Vilsmeier (hereinafter “Vilsmeier,” and made of record in the instant application by the Examiner in paragraph 8 of the Office Action), at Col. 1, ll. 31-50.

One solution to this curve-fitting problem is to decrease the width of each plate, correspondingly increasing the number of plates, to effect a more precise step-wise fit to an arbitrary curve. Vilsmeier discusses the problems inherent in this solution, as known in the art:

The number of blades of that can be used is limited. This is because each blade must be able to be independently shifted by mechanical means . . . This necessarily places an upper limit on the number of blades because too many of them would make the collimator, together with its support and activating mechanisms, too large and too heavy. (Vilsmeier, Col. 1, ll. 58-67).

By the combination of a unique and innovative placement of drive motors in a stacked circular configuration, use of detachable flexible blade drive transmission elements confined within narrow guide channels, and use of grooved guide plates to support and constrain the diaphragms, Applicants have solved a long-standing problem in the art, by providing many thin diaphragms to allow for close matching to arbitrarily curved tumor shapes while at the same time keeping the size of the collimator extremely compact. The plate widths in the Nunan collimator are 1.5cm, fifteen times as wide as the 1mm diaphragms utilized in the present invention. The present invention thus represents a significant advancement in the state of the art over Nunan, and the combination of collimator elements which achieve this significant advance, is not suggested or rendered obvious to one of ordinary skill in the art by the disclosure of Nunan.

Fee Payable for Independent Claims 2, 12, 13 and 18

In connection with the rewriting of claims 2, 12, 13, and 18 in independent form, a net addition of two independent claims has been made, beyond the number for which payment was previously made.

A check in the amount of \$78.00 payable to Commissioner of Patents and Trademarks is therefore enclosed in payment of the added claims fee.

Please charge any additional fee or amount properly payable in connection with the filing of this Amendment, to Deposit Account No. 08-3284 of Intellectual Property/Technology Law.

Conclusion

For the reasons stated in hereinabove, all claims 1-20 now pending in the present application, as amended herein, are fully distinguished over the prior art, and are in form and condition for allowance. Prompt and favorable action by the Examiner is therefore respectfully requested.

Respectfully submitted,



Edward H. Green, III
Registration No. 42,604
Attorney for Applicants

INTELLECTUAL PROPERTY/
TECHNOLOGY LAW
P. O. Box 14329
Research Triangle Park, NC 27709
(919) 419-9350
Attorney File: 4139-102